IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

CORDIS CORPORATION, Plaintiff, v. MEDTRONIC VASCULAR, INC., et al., Defendants.	)	C. A. No. 97-550 (SLR)
MEDTRONIC VASCULAR, INC., Plaintiff, v. CORDIS CORPORATION, et al., Defendants.	)	C. A. No. 97-700 (SLR)

MEDTRONIC AVE'S MEMORANDUM CONCERNING THE ADMISSIBILITY OF PRODUCT-TO-PRODUCT COMPARISONS

Cordis seeks to preclude Medtronic AVE from pointing out to the jury what will be obvious from the jury's own inspection: that Medtronic AVE's accused stents are in at least some ways very different from, and superior to, Cordis' alleged commercial embodiments. For the reasons set out below, Medtronic AVE should be allowed to point out the structural and performance differences between its stents and Cordis' to assist the jury in reaching a fully informed decision on the questions before it.

STATEMENT OF FACTS

In its Revised Memorandum Order of February 28 (Case Civ. No. 97-550-SLR; D.I. 1337), the Court granted Cordis' motion *in limine* to exclude *improper* product-to-product comparisons. In that same order, the Court specifically noted that such comparisons may be

appropriate in certain contexts, including to show invalidity of the patents in suit. (¶4(h)). The Court held that evidence of superiority is similarly admissible. (*Id.* at ¶4(i)).

A. Cordis' Attempts To Limit The Evidence In This Case

Cordis has now taken the position that it will not rely on the commercial success of Medtronic AVE's stents or accuse Medtronic AVE of copying. Based on this, Cordis argues that any evidence of product-to-product comparisons or product superiority should be excluded. For example, Cordis argued in its February 28, 2005 email to the Court as follows:

> (2) Medtronic AVE seeks clarification of certain evidence relating to the alleged superiority of its products over the claimed invention and/or Cordis' commercial [sic] embodiment. Your Honor has ruled this evidence is inadmissible for purposes of infringement [sic], but may be admissible if relevant to validity. We Medtronic AVE advised Medtronic AVE that Cordis will not rely on the commercial success of Medtronic AVE's stents as evidence of nonobviousness, and will not accuse Medtronic AVE of copying. This eliminates any possible relevance of any product-to-product comparisons or claims of superiority to the claimed invention under paragraphs (4)(h), (i), (k), and (m) of the Court's February 23, 2005 Memorandum Order (D.I. 1329) (the "Order"). For this reason, we expect Medtronic AVE will make no such comparisons in its opening remarks.

(Ex. A). It thus is clear that Cordis hopes to limit the evidence Medtronic AVE can introduce by itself agreeing not to press particular arguments. Cordis apparently assumes it can force Medtronic AVE to excise issues and evidence from its defensive case by making nips and tucks in its own. Cordis' assumption is incorrect for several reasons: (1) Cordis' arguments during its opening statements show that Cordis still maintains that the entire balloon expandable stent market owes its success to the '762 patent; (2) Cordis' commercial embodiments can help illustrate and give context to the claim language; (3) product-to-product comparisons can be appropriate to show a lack of nexus between the claims and the secondary considerations Cordis is asserting, as well as to show that Medtronic AVE's stents do not satisfy the substantially

uniform thickness limitation, and (4) Cordis cannot control what secondary considerations are at issue.

B. The Context of Medtronic AVE's Arguments

At the hearing on Friday, the Court asked Medtronic AVE to explain the context of the evidence it wishes to present. (Tr. 220). We refer the Court to Medtronic AVE's opposition to Cordis' motion *in limine* nos. 8-13, as well as the expert reports of Drs. Heuser and Wagoner cited therein (D.I. 1304 at Tab 8, pp. 3-8 and D.I. 1305 (Appendix) at Exs. H and I). Without repeating the entirety of that proffer here, Dr. Heuser generally may testify that the variably thick crown of Medtronic AVE's products is a significant design choice that distinguishes Medtronic AVE's products from the teaching of the Palmaz and Palmaz-Schatz patents of stents having a "substantially uniform thickness." Dr. Heuser will testify that this difference has had clinical significance in his practice. One important attribute of the variably thick crown design of the accused products is that they have a profile devoid of sharp edges which greatly facilitates the treatment of calcified and tortuous lesions. (D.I. 1305, Ex. H at 7-9; also attached hereto as Ex. A). Another important attribute is the ability of a stent to move easily through a vessel, or trackability (*id*. at 9), and to conform to the shape of the vessel (*id*. at 10). Dr. Heuser also may testify that another point of clinical significance attributable to the variably thick crown design is the ability to reach "side branches" of vessels that have already been stented, as well as the ability to pass one stent through another (as shown in the Schatz video). (*Id*. at 10-11). While Dr. Heuser can explain the features of Medtronic AVE's stents, they need to be placed in context to explain their clinical significance.

Another Medtronic AVE expert, Dr. Wagoner, may testify that the tapered crown configuration is an important feature of the Medtronic AVE stents which distinguishes it from

other stents. (*See* D.I. 1304 at Tab 8, at p. 4; D.I. 1305 at Ex. I at pp. 15-20; also attached hereto as Ex. B). Dr. Wagoner may testify that the variably thick leading surface facilitates delivery due to its "slipperiness" with the vessel. (Ex. B at 16). Dr. Wagoner's engineering judgment was reinforced by side-by-side examination of the accused stents with a Palmaz and Palmaz Shatz stent and clinical trials. (*Id*. at 16-17). Dr. Wagoner also cited real world examples of the acclaim for this feature, including the perception of the stent industry, the experience of clinicians, and his review of Dr. Schatz's testimony and video of a procedure. (*Id.* at 17-20).

As will be discussed below, the proffered testimony is relevant to both invalidity and noninfringement.

ARGUMENT

A. Medtronic AVE Should Be Permitted To Rebut Cordis' Argument That The Entire Stent Industry Is Built On Palmaz

While Cordis claimed in its email to the Court that it would only argue the commercial success of its own products, it told a very different story in its opening argument. In essence, Cordis took credit for the success of the entire stent industry. For example, Cordis' counsel asserted that:

- "the entire industry has been created based on the work of Dr. Julio Palmaz" (Tr. 129:1-3).
- "Before Dr. Palmaz did his work, there were – there was no stenting industry for balloon expandable stents, or other ideas out there. Now every year books are published on the new and expandable balloon expandable stents *based all on the work of Dr. Julio Palmaz*." (Tr. 145:9-14) (emphasis added).
- "Dr. Palmaz and Dr. Schatz created an industry . . ." (Tr. 145:23-24).

Cordis also argued about the improved function of the Palmaz-Schatz stent. For example, Cordis' counsel argued that: "And just expands very evenly. That's because it's smooth. It's of uniform thickness." (Tr. 130:23-24).

Cordis made these arguments notwithstanding its representation to Medtronic AVE and the Court, in response to Medtronic AVE's motion *in limine* no. 5, that it would not make arguments about the essence of its invention. (D.I. 1290 at 5; D.I. 1324). Contrary to its agreement, Cordis practically repeated verbatim its arguments from the first trial, suggesting once again that Dr. Palmaz invented the balloon expandable stent and that Medtronic AVE and the industry copied that idea. (Tr. 120:7-122:3). Thus, Cordis' real story at trial was a far cry from relying only on the success of Cordis' own products.

Given that Cordis crossed well over the line that it set for itself, Medtronic AVE should be permitted to rebut Cordis' assertion that the entire industry is built on Palmaz and his ideas. Medtronic AVE should be permitted to show that the industry immediately moved to Medtronic AVE's stents, as soon as they became available, due to their improved performance and deliverability. It also should be permitted to offer evidence of the improved functionality of its products over Palmaz-Schatz.

B. The Proffered Testimony Is Relevant To Give Context To The Claimed Inventions

While infringement is determined by comparing the accused devices to the claims, reference about the commercial embodiments can be probative to explain or illustrate the claim language. *See Afros SPA v. Krauss-Maffei Corp.*, 671 F. Supp. 1402, 1435, n.33 (D. Del. 1987), *aff'd without op.*, 848 F.2d 1244 (Fed. Cir. 1988). In *Afros SPA,* Judge Schwartz found that it was relevant for the infringement analysis to compare parties' engineering drawings due to the parties' stipulation that the patentee's mixing heads conformed to the '335 patent drawings and

descriptions. The Court held that "the commercial embodiments are good illustrations of the infringement and provide additional evidence to support the Court's findings." (*Id.*). As the Court may recall, the parties at the *ACS v. Medtronic* trial relied on the commercial embodiments of the patents to illustrate certain features. So, too, here, the commercial embodiments help illustrate stents with substantial uniform thickness and demonstrate why the Medtronic AVE stents do not infringe that limitation.

At the hearing, the Court suggested that it would be improper to compare the accused products to a preferred embodiment. Because substantially uniform thickness is a requirement of all asserted claims, however, the Palmaz-Schatz is not only a preferred embodiment in this respect, it is the only embodiment. The sharp, leading edge is a characteristic of a stent with substantially uniform thickness.

At the end of the day, the jury will be instructed that to determine infringement, it must compare the accused products to the claims. Medtronic AVE does not contend otherwise. Medtronic AVE respectfully submits, however, that it can be proper for the jury to consider the features of the commercial embodiments with walls with substantially uniform thickness to understand whether Medtronic AVE's stents meet the substantially uniform thickness requirement.

The clinical evidence that Cordis seeks to suppress – *e.g.*, that the variable thickness of the Medtronic AVE stents improves performance over the earlier Palmaz-Schatz stents – supports Medtronic AVE's showing that the variance in thickness is not *de minimus* or due to manufacturing tolerances, but rather is an intentional design feature that has clinical significance. That clinical significance supports Medtronic AVE's contention that its accused stents do not

have a wall of "approximately uniform thickness." In other words, the lack of uniformity is a purposeful design feature that results in superior performance.

C. The Presence Or Absence of Secondary Factors Can Be Relevant To The Obviousness Determination

Cordis should not be permitted to pick and choose the secondary considerations here that may be relevant to obviousness or non-obviousness. While Cordis bears the burden of proof on the secondary indicia of non-obviousness, Medtronic AVE can rebut Cordis' evidence by pointing to the secondary considerations which counter Cordis' position. For example, Medtronic AVE can point out which factors do not favor Cordis.

The fact that Cordis fails to show certain secondary considerations bolsters a showing of obviousness. Indeed, Cordis's contrary position on this issue represents a stark turnaround from the position it apparently took on this same issue in a past case when it was trying to invalidate rather than defend a patent.

In *Scimed Life Sys. v. Johnson & Johnson*, 225 F. Supp. 2d 422, 441 (D. Del. 2002), Cordis presented evidence at trial of the very factors it seeks to exclude in this case, including the absence of a long felt need, the success of a different patented product, and independent invention by others. In denying Scimed's motion for judgment as a matter of law, the Court agreed with Cordis that a demonstrated lack of secondary considerations can be probative of invalidity:

> In addition, defendants demonstrated the lack of secondary considerations of non-obviousness, including the absence of a long-felt need for a stent that compensates for foreshortening (D.I. 267 at 649-53; D.I. 269 at 1476-78, 1498-1500), the success of the flexible Multi-Link stent, which is based on a patent that constitutes prior art to the Medinol patents (D.I. 266 at 621; D.I. 270 at 1546-51; DX 18), and independent invention of the stents encompassed by the asserted claims by others. (D.I. 271 at 1718-24; DX 12). The record reflects substantial evidence that supports

> the jury's finding by clear and convincing evidence that the asserted claims of the '303 and '018 patents are invalid for obviousness over the prior art. Thus, the court shall deny plaintiffs' motion for judgment as a matter of law on this ground.

225 F. Supp. 2d at 441.

As it did for Cordis in the *Scimed* case, so too in this case, the "lack of secondary considerations of non-obviousness" will help Medtronic carry its burden of presenting "clear and convincing evidence that the asserted claims . . . are invalid." (*Id.).*

D. The Evidence Cordis Seeks To Exclude Is Relevant To Show The Lack Of Nexus Between Cordis Products And The Patented Invention.

When a patentee offers evidence of commercial success of its own product to support its contention of non-obviousness, it must show a nexus between the commercial success and the patented invention. *Pentec, Inc. v. Graphic Controls Corp.*, 776 F.2d 309, 315 (Fed. Cir. 1985) (for the commercial success of the claimed invention to be given substantial weight, a nexus must be established between it and the claimed invention). *See also Simmons Fastener Corp. v. Illinois Tool Works, Inc.*, 739 F.2d 1573, 1575 (Fed. Cir. 1984) (a "nexus between the merits of the claimed invention and the evidence of secondary considerations is required in order for the evidence to be given substantial significance in an obviousness decision").

Medtronic AVE should be permitted to demonstrate the lack of nexus, by evidence establishing that the success of the alleged commercial embodiment was due to something other than the patented invention. *See, e.g., Cable Elec. Prods. v. Genmark, Inc.*, 770 F.2d 1015, 1026 (Fed. Cir. 1985) (evidence failed to establish that plaintiff's commercial success was "in some way been due to the nature of the claimed invention") (overruled on other grounds, *Midwest Indus., Inc. v. Karavan Trailers, Inc.*, 175 F.3d 1356, 1359 (Fed. Cir., 1999)).

In this regard, the product-to-product comparison is central to showing that no nexus exists between the secondary considerations Cordis is asserting and the claimed invention. For example, to show that commercial success has any relevance, Cordis must show that it practices the invention, *i.e.* it that its stents are substantially uniformly thick. Medtronic should then be allowed to show that the substantial uniform thickness of the product was a ***drawback*** that led the market to move immediately to Medtronic AVE's product as soon as it became available, because Medtronic AVE's product was far more deliverable due, among other reasons, to its rounded edges which are not substantially uniformly thick. This also demonstrates that Cordis's short-lived success was due to other factors, such as the first to market phenomenon, heavy marketing and securing insurance reimbursements.

E. Cordis Should Not Be Permitted to Assert Some Secondary Considerations And Seek To Exclude Others; All Secondary Considerations Are Relevant

Medtronic AVE challenges certain of the asserted claims as obvious. The ultimate determination of whether an invention was obvious at the time it was made depends, in part, on objective secondary considerations such as commercial success, satisfaction of a long-felt need, skepticism and copying. *Graham v. John Deere Co.*, 383 U.S. 1, 17-18, 86 S. Ct. 684, 694, 15 L. Ed. 2d 545 (1966); *Demaco* Corp. *v. F. Von Langsdorff Licensing Ltd.*, 851 F.2d 1387, 1392 (Fed. Cir. 1988) (commercial success); *Uniroyal, Inc. v. Rudkin-Wiley Corp.*, 837 F.2d 1044, 1054 (Fed. Cir. 1988) (long-felt need); *Pro-Mold & Tool Co. v. Great Lakes Plastics, Inc.*, 75 F.3d 1568, 1574 (Fed. Cir. 1996) (copying). Cordis has indicated it will seek to defend the patents, at least in part, by offering evidence of certain secondary considerations of non-obviousness.

Graham v. John Deere Co. identifies "several basic factual inquiries" as necessary in making a determination on obviousness under Section 103. These include the content of the prior art, the differences between that art and the claimed subject matter, and the level of ordinary skill in the subject art. 383 U.S. at 17. In addition, *Graham* suggests that certain "secondary considerations" which "give light to the circumstances surrounding the origin of the [patented] subject matter" may Medtronic AVE relevancy as "indicia of *obviousness or nonobviousness*." (*Id.* at 17-18 (emphasis added)).

Evidence on these secondary considerations must be taken into account, "not just when the decisionmaker remains in doubt after reviewing the art." *Stratoflex, Inc. v. Aeroquip Corp.*, 713 F.2d 1530, 1539 (Fed. Cir. 1983) ("It is jurisprudentially inappropriate to disregard any relevant evidence on any issue in any case, patent cases included. Thus evidence rising out of the so-called 'secondary considerations' must always when present be considered en route to a determination of obviousness"). *See, e.g., Iron Grip Barbell Co. v. York Barbell Co.*, 392 F.3d 1317, 1319 (Fed. Cir. 2004) (quoting *Vandenberg v. Dairy Equip. Co.*, 740 F.2d 1560, 1567 (Fed. Cir. 1984)) ("in 'determining the question of obviousness, inquiry should always be made into whatever objective evidence of nonobviousness there may be.'"); *Ashland Oil, Inc. v. Delta Resins & Refractories, Inc.*, 776 F.2d 281, 307 (Fed. Cir. 1985) (where the district court's opinion does not consider evidence of secondary considerations in the record, the Federal Circuit may, as a matter of law, consider such evidence in reviewing the ultimate conclusion of obviousness/nonobviousness entered by the trial court without the need for a remand.); *Jones v. Hardy*, 727 F.2d 1524, 1530 (Fed. Cir. 1984) (objective indicia of non-obviousness, when present, must always be considered before a legal conclusion under section 103 is reached); *Stratoflex, Inc. v. Aeroquip Corp.*, 713 F.2d 1530, 1538 (Fed. Cir. 1983) (evidence rising out of

the so-called "secondary considerations" are always pertinent when attempting to make a judgment of obviousness).

Indeed, reference by the Supreme Court's *Graham* case itself to "indicia of *obviousness or nonobviousness*" underscores this fact. *See* 383 U.S. at 17 ("Such secondary considerations as commercial success, long felt but unsolved needs, failure of others, etc., might be utilized to give light to the circumstances surrounding the origin of the subject matter sought to be patented. As indicia of obviousness or nonobviousness, these inquiries may have some relevancy").

Cordis argued in its opening statement that at the time it was investing in the Palmaz-Schatz stent, "the medical community just shook its head . . . [they said] this is a passing fancy. It will never last. It's dangerous." (Tr. 127:23-128:2). Medtronic AVE should be permitted to show that this was just not true. It should be permitted to put on evidence that many stent designers, including Medtronic AVE, were filing for stent patents and designing stents better than the patented stents at the time of the alleged skepticism. It also should be permitted to show that there was no long felt need for the patented features.

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CERTIFICATE OF SERVICE

I, the undersigned, hereby certify that on March 5, 2005, I electronically filed Medtronic AVE's Memorandum Concerning The Admissibility Of Product-To-Product Comparisons without exhibits which will send notification of such filing to the following:

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